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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,100	11/12/2003	Seymour H. Fein	SER-001	7710

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EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
01/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/706,100	FEIN, SEYMOUR H.	
	Examiner	Art Unit	
	ANDREW D. KOSAR	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6,7,9 and 27-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6,7,9 and 27-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/15/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments/Arguments

Applicant's amendments and arguments filed April 8, 2008 are acknowledged. Applicant's response to the Rule 105 Request, filed August 15, 2008 is acknowledged. Any rejection and/or objection not specifically addressed below in original or modified form is herein withdrawn.

Applicant's arguments are generally iterative of previous traversals, in that Applicant asserts the claims have description and enablement. In the traversal of the 112 2nd ¶ rejection, Applicant states, "The inventions claimed herein do not involve some specific method or structure for achieving the claimed desmopressin blood concentration profiles. This is the domain of the skilled mechanic. Applicant's claimed invention does not involve the specific mechanism or structure through which the dose form achieves the blood concentration, save that they meet the limitations as recited in the various presented claims." (page 17). Applicant further states, "Accordingly, no step essential to define applicant's invention is omitted. The specific structures and chemistries exploited to achieve the blood levels recited are no more a part of the invention than the specific way the desmopressin in the dosage forms is manufactured." (page 17).

In light of the myriad of desmopressin compositions well known in the art, and applicant's statement that the elements of the composition are nonessential to the description of compositions that would function as required, the examiner withdraws the rejections, as the artisan is aware of various dosage forms of desmopressin with the requisite quantity of desmopressin, and it is well settled that, "the discovery of a previously unappreciated property of

a prior art composition, or of a scientific explanation for the prior art's function does not render the old composition patentably new to the discoverer. *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977)." Applicant is additionally directed to *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980), *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972) and *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.) with regards to inherency.

Further, Applicant's statements assert that the composition make up is irrelevant, and the PTO has shown "a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." (MPEP § 2112.01). A proper rebuttal requires evidence that the prior art composition does not necessarily possess the characteristics of the claimed product. Because Applicant has no specific composition exemplified, the examiner properly concludes that any prior art composition would anticipate, or render obvious, the instantly claimed composition.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 9 and 27-31 are rejected under 35 U.S.C. 102(b) as being anticipated by FJELLESTAD-PAULSEN.

Fjellestad-Paulsen teaches a variety of desmopressin compositions, including 2 μg subcutaneous (e.g. page 15), intranasal (e.g. page 15 and Table 2, page 25). Intranasal dosages were 5 or 10 μg. Fjellestad-Paulsen additionally teaches sublingual, oral, transdermal, intratracheal, aerosol, rectal and ocular administrations of desmopressin are known in the art (spanning pages 15 and 16).

Fjellestad-Paulsen teaches IV solution for bolus comprising 4 or 5 μg desmopressin (Table 7, spanning pages 50 and 51). Additionally, Fjellestad-Paulsen teaches 2 μg + 3.5 ml NaCl (page 37 and Table 7) and a 2 μg subcutaneous composition (Table 7). It is noted that subcutaneous administration is a form of intradermal administration. Assuming *arguendo* that there is a distinction, nothing precludes intradermally injecting the NaCl composition intradermally. "Furthermore, it has been shown that by optimizing concentration, volume and technique of administration by the nasal route a significant increase of the biovailability can be reached (citing Harris *et al.* 1988)." (page 49).

Fjellestad-Paulsen additionally teaches that "numerous studies have confirmed the superiority of dDAVP in the treatment of central or neurogenic diabetes in both adults and children because of its prolonged antidiuretic effect and lack of side effects. The most prevalent route of administration is intranasal (i.n.). Children and adults patients usually require 5-20 μg

dDAVP intranasally once or twice daily and infants are treated with smaller doses ranging from 1 to 15 μg once or twice daily." (page 14, citations omitted). "The antidiuretic activity of dDAVP has also resulted in its use in nocturnal enuresis in children and nocturia in adults." (page 14, citations omitted). "Other clinical applications of dDAVP include its use to increase the yield of factor VIII in blood donors, in the treatment of mild hemophelia A and von Willebrand disease and in patients undergoing cardiac surgery to reduce early postoperative bleeding." (page 14, citations omitted).

Claims 29, 30, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by SIBALIS (US Patent 4,878,892).

Sibalis teaches electrolytic transdermal delivery of polypeptides using a transdermal patch (e.g. claim 1 and 14), specifically embodying desmopressin (claim 15).

As discussed above, Applicant has no specific composition exemplified, the examiner properly concludes that any prior art composition would anticipate the instantly claimed composition and that the requisite function is inherent.

Claims 29, 30, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by BANNON (US Patent 5,135,480).

Bannon teaches desmopressin formulated as a gel with karaya gum to achieve a concentration of 3 mg/ml (e.g. Example 5, column 9) as well as a transdermal device (claim 9) where the concentration of the active is 0.1 to 15% w/v based on the hydrophilic medium (e.g. claim 12).

As discussed above, Applicant has no specific composition exemplified, the examiner properly concludes that any prior art composition would anticipate the instantly claimed composition and that the requisite function is inherent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 4, 6, 7, 9 and 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over FJELLESTAD-PAULSEN, *supra*, in view of SIBALIS or BANNON.

The teachings of Fjellestad-Paulsen are presented *supra*.

Sibalis teaches electrolytic transdermal delivery of polypeptides using a transdermal patch (e.g. claim 1 and 14), specifically embodying desmopressin (claim 15).

Bannon teaches desmopressin formulated as a gel with karaya gum to achieve a concentration of 3 mg/ml (e.g. Example 5, column 9) as well as a transdermal device (claim 9) where the concentration of the active is 0.1 to 15% w/v based on the hydrophilic medium (e.g. claim 12).

The difference between the instant claims and the prior art is that while each of the cited references teaches desmopressin for transdermal delivery, none specifically enumerates the claimed quantity (0.5 ng to 20 μg) in the composition.

Dose size is an extrinsic property that does not materially alter the composition, which is a composition comprising desmopressin. Further, Bannon teaches that 0.1-15% w/v is used, and further that a concentration of 3 mg/ml was formulated in the example. Thus, Bannon overlaps

with the instantly claimed range of desmopressin in the composition. Sibalis does not provide any specific quantity, and thus embraces all quantities from one molecule of desmopressin to the saturation limit of the composition formed.

It would have been obvious to have formulated a transdermal patch/gel with any amount of desmopressin, as the art provides broad and non-limiting ranges for the concentration of the active. One would recognize the need for smaller dosages for smaller patients, e.g. children and infants, and thus it would have been obvious to have formulated the composition in smaller quantities. One would have a reasonable expectation for the predictable outcome that the composition would be suitable for transdermal delivery, as the various teachings in the art provide detailed explanation as to how to formulate transdermal compositions, including compositions of desmopressin.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 4, 6, 7, 9 and 27-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-27 of copending Application No. 12/173,072 (amended claims of 7/15/08). Although the conflicting claims are not identical, they are not patentably distinct from each other because the compositions used in the method of '072 anticipate the instant claimed compositions. It is noted that '072 is a continuation of the instant application and thus necessarily uses the same compositions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3, 4, 6, 7, 9 and 27-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-29 of copending Application No. 12/173,074 (amended claims of 7/15/08). Although the conflicting claims are not identical, they are not patentably distinct from each other because the articles of manufacture of '074 anticipate the instant claimed compositions being desmopressin compositions of 50 ng to

10 μg (e.g. claim 20), where the composition is for transmucosal, transdermal, intradermal, subcutaneous administration (e.g. claims 22-25). It is noted that '072 is a continuation of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/
Primary Examiner, Art Unit 1654